

JUN 12 1996

Dr. Eric L. Foxman
Bioforce of America, Ltd.
P.O. Box 507
Kinderhook, New York 12106

Dear Dr. Foxman:

This is in response to your letter of March 28, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statements for your products:

"Stinging Nettle"

Rheumatic conditions can be aggravated by excessive uric acid. Stimulation of uric acid secretion can help provide symptomatic relief. A. Vogel's Stinging Nettle helps to stimulate uric acid secretion.

"Bronchosan"

Irritated throat or lungs can lead to fits of coughing. The components of A. Vogel's Bronchosan help to soothe the throat and lungs even in cases of Bronchitis.

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these product suggest that they are intended to treat or mitigate disease, in that (1) "Stinging Nettle" claims to help "stimulate uric acid secretion" which can provide symptomatic relief of rheumatic conditions and (2) "Bronchosan" claims to help "soothe the throat and lungs even in cases of Bronchitis." Therefore, these claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that they are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

We further note that a label attached to your March 28, 1996 submission does not bear the disclaimer statement required by section 403(r)(6)(C) of the act (e.g., the label for "Gastrosan"). Section 403(r)(6)(C) of the act requires that when a statement of nutritional support is made for dietary supplements, the statement must contain, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This

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product is not intended to diagnose, treat, cure, or prevent any disease." Marketing products with claims of how the product affects the structure or function of the body without this disclaimer subjects these products to regulation as drugs.

Sincerely yours,

**James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition**

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, New York District Office, Office of Compliance, HFR-NE140

**FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200**